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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

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06/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,344	JIRA ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-16* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-9 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3, and 5-16 are pending in the application.

2. In the prior action, the Final action mailed on December 18, 2006, claims 1, 3, and 5-16 were pending in the application, with claims 1, 3, 5-9, and 13-16 under consideration and rejected, and claims 10-12 withdrawn as to non-elected inventions.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 18, 2007 has been entered.

In the Response of April 18, 2007, the Applicant amended claims 1, 3, 5, and 7.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **(New Rejection)** Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on a multivalent antiviral vaccine comprising "one or more" antigens. It is not clear what is covered by this claim. Because the claim indicates that the vaccine is multivalent, the claim is implying that multiple antigens from different influenza viruses are present in the composition. However, the claim also indicates that the

composition may comprise only one such antigen. See e.g., the "one or more" language in line 1 of the claim. In view of the conflict between these two claim limitations, it is not clear what the scope of the claim is.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **(Prior Rejection- Withdrawn)** Claims 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo et al. (U.S. 5,506,271). In view of the amendment to the claims, the rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claims 3, 5-9 and 13-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo as applied to claim 1 above, and further in view of either of Felici et al. (U.S. 5,994,083), or Ooyama et al. (EP 0 775 494). In view of the amendments to the claims, the rejection is withdrawn.

9. **(New Rejection)** Claims 1, 3, 5-9, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo (U.S. 5,506,271) further in view of either of Felici et al. (U.S. 5,994,083), or Ooyama et al. (EP 0 775 494), and further in view of the teachings of Rios et al. (U.S. 6,383,806) and Lathe et al. (U.S. 6,024,953). The claims have been amended to read on

compositions comprising heat denatured viral antigens (such as those described by Meruelo) and pathogen-infected denatured cells. The teachings of Meruelo, either alone or in combination with Felici and/or Ooyama, do not teach or suggest the inclusion of such denatured cells in the disclosed immunogenic compositions.

However, teachings in the art indicate that antiviral immunogenic compositions may be made both through the inactivation of the viral antigens, and through inactivation of cells infected with the target virus. See e.g., Rios, column 18, lines 5-17; and Lathe, column 9, lines 41-45. Moreover, both of these references indicate that the cells may be inactivated by the same process used for the inactivation of the virus itself. In view of these teachings, it would have been obvious to those of ordinary skill in the art that the inactivation step (the heat denaturing in the presence of hypericin) of Meruelo could be applied both against the isolated virus, yielding a composition comprising the denatured viral antigen, or against a virus infected cell, yielding a composition comprising both the denatured viral antigen and the denatured virus-infected cells. Those of ordinary skill in the art would have had a reasonable expectation of success in such an application based on the teachings of Lathe and Rios indicating that the infected cells may be so used, and on the teachings of Meruelo, which indicate that the disclosed methods may be applied with any protein or peptide containing composition. Columns 2-3. Those of ordinary skill in the art would also have been motivated to make the compositions of Meruelo through the use of inactivating the infected cells (thereby denaturing the cells) such that the number of steps to produce the composition is reduced (i.e., the new method avoid the step of isolating the virus from the host cells used for viral propagation). The combined teachings of these references therefore render the claimed methods obvious.

10. **(New Rejection)** Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto (U.S. 6,544,528) in view of Meruelo (U.S. 5,506,271) and further in view of either of Felici et al. (U.S. 5,994,083), or Ooyama et al. (EP 0 775 494). These claims read on dry immunogenic vaccines comprising an immunogen denatured at higher than 60° C and formulated as an oral pill, where the immunogen comprises pathogen infected denatured cells.

Yamamoto teaches the making of vaccine compositions through the inactivation of either of viruses or of virus-infected cells. Column 6. The reference teaches that such cells may be inactivated through the use of heat, and that they may be formulated for oral administration. Column 6, lines 9-10, and 27-32. The reference also indicates that the vaccines are "typically combined with an adjuvant," thereby indicating to those of ordinary skill in the art that the composition may or may not comprise the adjuvant. However, the reference does not teach the inactivation of the cells at temperatures of higher than 60° C or the formulation into oral pills.

The teachings of Meruelo have been described previously. This reference does teach the inactivation of vaccine immunogens at temperatures of greater than 60° C. Moreover, the reference indicates that the described inactivation method may be applied for the preparation of any "protein- or peptide-containing agent" such as viruses, including the FIV virus. Column 3, lines 9-10 and 25-37. Because the Meruelo reference indicates that the disclosed method may be applied to any such vaccine composition, and as Yamamoto indicates that the virus infected cells described therein may be inactivated with heat, it would have been obvious to those of ordinary skill in the art to combine the teachings of these references for the production of a heat

inactivated anti-viral vaccine. However, the references do not teach or suggest the formulation of the vaccines as pills.

Nonetheless, because each of the Meruelo and Yamamoto references teach that the indicated vaccines may be orally administered, and as Felici and Ooyama references provide examples of such oral formulations, including formulations as pills (see e.g., discussion on page 8 of the August 23, 2005 action), it would have been obvious to those of ordinary skill in the art to use such formulations for the oral vaccines suggested by Yamamoto and Meruelo. The combined teachings of the references therefore render the claimed inventions obvious.

Conclusion

11. No claims are allowed.

12. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Yoshizawa et al., JP 57175127 (English abstract attached). This reference also teaches heat-inactivated antigens, heated at 60° for 10 hours. The teachings of this reference are cited as close prior art.
>
> Kronenberg (U.S. 4,568,542). This reference teaches the inactivation of virus-infected cells, and the use thereof in vaccine compositions. However, the reference does not teach the use of heat inactivation at greater than 60° C, or the oral formulation of such vaccines.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner